

REMARKS

Rejection of the claims under 35 USC §102:

Claims 1-1, 4, 6-8, 12-27, and 29 have been rejected under 35 U.S.C. 102(b) as being anticipated by Twist et al. (U.S. Patent 5,633,230). The Action states that the only active step recited in the base claim, is “inserting an injection solution containing the protein or peptide into the lumen of an efferent or afferent vessel of the target tissue.” Applicants respectfully disagree. The “inserting” of the above step is actively qualified in that the injection volume and rate must “cause transient increased vascular permeability in the target tissue, increased extravascular fluid volume within the target tissue, and swelling of the target tissue”.

The action states that the solution taught by Twist et al. is hypertonic and would therefore cause a transient increase in vascular permeability. However, the claims recite that it is the volume and rate of the injection that causes increased vascular permeability. As shown by the 1.132 Declaration filed 4/21/2008, Twist et al. do not inject a volume sufficient to cause vascular permeability. Therefore, Twist et al. do not teach all the limitations of the Applicants’ claim.

On page 4 of the action, the Examiner suggests that it would have been obvious to use an increased volume and injection rate to cause an increase in vessel permeability similar to that accomplished by the hypertonic injection solution used by Twist et al. Applicants note that the solution used by Twist et al. is not hypertonic. With respect to the injection solution of Twist et al. causing increased vessel permeability, Applicants can find no teaching in 5,633,230, for either a hypertonic injection solution or a desire for or observation of increased vessel permeability, increased extravascular fluid volume within the target tissue, or swelling of the target tissue. A search of 5,633,230 for the terms hypertonic or permeability (or variations thereof) yielded no results. Twist et al. further teach, at column 8 lines 6-23, the that injection solution is preferably isotonic or hypotonic (“administered in distilled water”, line 16).

Claims 1-2, 4, 6-8, 12-27, 29, and 30 have been rejected under 35 U.S.C. 102(b) as being anticipated by Goddard (U.S. Patent 5,602,094). The Action states that the only active step recited in the base claim, is “inserting an injection solution containing the protein or peptide into the lumen of an efferent or afferent vessel of the target tissue.” Applicants respectfully disagree. The “inserting” of the above step is actively qualified in that the injection volume and rate must “cause transient increased vascular permeability in the target tissue, increased extravascular fluid volume within the target tissue, and swelling of the target tissue”.

Double Patenting:

Claims 1-2, 4, 6-8, 12-27, 29, and 30 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 14 of U.S. Patent 7,144,869 in view of Rosenberg et al. (US 2002/0064520). Applicants respectfully disagree. US 2002/0064520 teaches modification of viral nucleocapsids through attachment of immuno-protective elements, targeting elements, and/or cell-entry elements. US 2002/0064520 further teaches at paragraph 0069 that their vectors are administered in vivo by methods that are well known in the art. However, US 2002/0064520 fails to show any in vivo delivery, showing only in vitro delivery of their vectors to cells. Therefore, the teaching of US 2002/0064520 expresses only the desire to deliver their vector in vivo and no mechanism by which there vectors can be delivered to extravascular cells in vivo. 7,144,869 was filed after the publication of US 2002/0064520 teaches only delivery of naked nucleic acid. Thus, prior to Applicants’ invention, a method to deliver proteins or peptides to extravascular cells in vivo was not known.

Claims 1-2, 4, 6-8, 12-27, 29, and 30 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 09/000,533 in view of US 2002/0064520. Applicants respectfully note that Application No. 09/000,533 was abandoned as of April 8, 2002 and is therefore not copending.

Appl. No. **10/628,792**  
Amdt. Dated **8/27/2008**  
Reply to Office action of **05/30/2008**

The Examiner's rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1-2 and 4, 6-8, and 12-30 should be allowable.

Respectfully submitted,

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I hereby certify that this correspondence is being  
transmitted to the USPTO on this date: 08/27/2008.

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